STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
MISSOURI CVS PHARMACY, LLC d/b/a	)	Complaint No. 2010-002350
CVS/PHARMACY #5645	)	
930 N. Belt Highway	)	
St. Joseph, Missouri 64506	)	
	)	

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND MISSOURI CVS PHARMACY, LLC d/b/a CVS/PHARMACY #5645

Come now Missouri CVS Pharmacy, LLC d/b/a CVS/Pharmacy #5645 ("Respondent" or "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("AHC") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of

discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2004023122 at the time of the events herein described and after a change of ownership, the new permit number is 2009008060, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Missouri CVS Pharmacy, LLC d/b/a CVS/Pharmacy #5645 ("Respondent") is licensed by the Board as a pharmacy as defined by §338.010 RSMo. It operated under Permit No. 2004023122 at the time of the incidents herein. The pharmacy has since undergone a change of ownership and is now operating under Permit No. 2009008060. Respondent's license was active at all times relevant herein.

[1] All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

3. The Board investigated Respondent in 2008 and determined that significant losses of controlled substances had occurred due to technician diversion. A loss of 1,675 Hydrocodone/APAP 10/500 tablets was found.

4. On May 13, 2009, the Board sent Respondent an Administrative Letter of Warning which reminded Respondent of its duties under state and federal laws and made clear that future violations of these laws would result in disciplinary action being taken by the Board.

5. As a result of the 2008 investigation and the letter of warning issued by the Board, Inspector Shawn Newton conducted a follow-up audit in early 2009.

6. On February 18, 2009, Inspector Newton conducted her audit which revealed overage discrepancies.

7. Respondent disagreed with the findings and requested that the Board re-audit the pharmacy at a time when a CVS employee could be present to witness the counts.

8. On January 23, 2010, Inspector Newton conducted another audit of Respondent with Pharmacy Supervisor Joe Farrar present and participating in the activity.

9. The January 23, 2010, audit revealed a significant loss of controlled substances as set forth in paragraph 18.

10. On or about May 7, 2010, Mr. Farrar forwarded to the Board a DEA-106 form entitled Report of Theft or Loss of Controlled Substances and a Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") form entitled Report of Loss or Theft of Controlled Substances, both of which acknowledged that 28,174 tablets of controlled substances were missing from the pharmacy due to employee theft or diversion.

11. On or about May 17, 2010, the Board assigned Inspector Newton to further investigate the losses which occurred at the pharmacy.

12. Inspector Newton conducted an investigation on behalf of the Board. After completing the investigation, but prior to completing an investigation report, Inspector Newton left employment with the Board. On or about July 29, 2010, Inspector Tom Glenski finalized an Investigation Report dated July 21, 2010 based on Inspector Newton's findings.

13. On or about August 23, 2010, Respondent entered into an agreement with the BNDD in which it admitted violating statutes and regulations which provide standards for the handling and dispensing of controlled substances in Missouri and agreed to have their Controlled Substances Registration placed on probation for a period of four (4) years.

14. The Board met to review Inspector Glenski's Investigation Report dated July 21, 2010, as well as other facts, investigative information and allegations concerning the acts and conduct of Respondent.

15. Based upon its review, the Board, pursuant to §338.055, RSMo concluded that the Respondent engaged in conduct which would be grounds for disciplinary actions by the Board as follows:

Loss of Controlled Substances

16. Following Respondent's investigation, Pharmacy Technician M.P. admitted to stealing the following drugs from the Respondent pharmacy: Hydrocodone/APAP 10/325 and Hydrocodone/APAP 10/500.

17. Hydrocodone-APAP is a schedule III controlled substance.

18. During her January 23, 2010 audit, Inspector Newton and Mr. Farrar agreed on the following audit results:

Audit Results				
Time Period: 5/1/09 to 1/23/10				
Drug & Strength	**Total Accountable For**	**Total Accounted For**	**Difference**	**Percent Difference**

Hydrocodone/APAP 10/500	168220	155558	**-12662**	**-7.5%**
Hydrocodone/APAP 5/500	94700	94485	-215	-0.2%
Hydrocodone/APAP 7.5/500	104640	104901	261	0.2%
Hydrocodone/APAP 7.5/750	6871	6732	-139	-2.0%
Hydrocodone/APAP 10/325	64261	51720	**-12541**	**-19.5%**
Alprazolam .5mg	61269	61497	228	0.4%
Alprazolam 1mg	34106	33736	-370	-1.1%
Alprazolam 2mg	1820	1818	-2	-0.1%
Diazepam 2mg	2660	2785	125	4.7%
Diazepam 5mg	7300	7218	-82	-1.1%
Diazepam 10mg	11802	11857	55	0.5%
Phentermine 37.5mg	20902	20497	-405	-1.9%
		Total Short	26,416	
		Total Over	669	

19. Based on the significant losses of Hydrocodone/APAP 10/500 and Hydrocodone/APAP 10/325 as shown in paragraph 18, Mr. Farrar and CVS Loss Prevention Specialist Steve Sullivan started an internal investigation.

20. After January 23, 2010, and during the investigation conducted by Mr. Farrar and Mr. Sullivan, losses continued to occur at the pharmacy.

21. The source of the losses was not discovered until May 5, 2010 when Respondent determined that Pharmacy Technician M.P. was stealing controlled substances.

22. M.P. admitted that she had stolen controlled substances by placing single stock bottles in her purse at least twice a week.

23. M.P. admitted that between September of 2009 and May of 2010, she had taken at least 80 stock bottles of Hydrocodone/APAP 10/500 and at least 7 stock bottles of Hydrocodone/APAP 10/325.

24. M.P. was terminated from employment at the Respondent pharmacy on or about May 7, 2010.

25. Despite the fact that Respondent had been warned about its conduct that led to a loss of controlled substances less than one year earlier, losses of controlled substances to continued to occur.

26. On or about May 7, 2010, Respondent filed DEA and BNDD loss reports listing the following losses from the pharmacy:

Drug	Amount Lost
Hydrocodone/APAP 10/325	16,534
Hydrocodone/APAP 10/500	11,640

27. Respondent's loss reports to the DEA and BNDD on or about May 7, 2010 show that a large number of controlled substances were diverted from the pharmacy after January 23, 2010 and during Respondent's internal investigation.

28. After January 23, 2010, Respondent was aware that Hydrocodone/APAP 10/325 was being diverted from the pharmacy, yet 4,000 more tablets were diverted prior to discovering who was responsible.

29. In its August 23, 2010 Settlement Agreement with BNDD, respondent admitted that it "did not provide adequate physical security that was commensurate with the quantities of controlled substances received and handled during normal business hours."

30. Further, Respondent admitted "[t]he Pharmacy did not provide effective controls to detect and prevent the diversion of controlled substances in violation of 21 CFR 1301.71(a) and 19 CSR 30-1.031."

Statutes and Regulations Violated

31. Respondent was and continues to be responsible for complying with all state and federal laws pursuant to Section 338.250, RSMo which states, in relevant part:

...Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed....

32. 19 CSR 30-1.031(1)-(2) states as follows:

(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032 – 19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

(2) Physical Security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly. 19 CSR 30-1.031(1)-(2).

33. From at least September of 2009 through May 5, 2010, Respondent failed to implement effective security controls for its schedule III controlled substances.

34. 19 CSR 30-1.034(1) states in part as follows:

(1) Physical Security.

> (B) . . . pharmacies may disperse [controlled substances listed in Schedules III, IV, and V] throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. 19 CSR 30-1.034(1)(A)-(B).

35. 21 C.F.R. §1301.75(b) states in part as follows:

(b) . . . pharmacies and institutional practitioners may disperse [controlled substances listed in Schedules III, IV, and V] throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. 21 C.F.R. §1301.75(b).

36. Respondent failed to provide adequate physical security upon its premises by failing to effectively disburse Hydrocodone, a schedule III controlled substance, in such a manner as to obstruct the theft or diversion of the same.

37. 21 C.F.R. §1301.71(a) states as follows:

> (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§1301.72 – 1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections. 21 C.F.R. §1301.71(a).

38. 20 CSR 2220-2.010(1)(H) states as follows:

> (H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility. 20 CSR 2220-2.010(1)(H).

39. Respondent's conduct herein described, as highlighted by its own admissions, is in violation of § 338.250, RSMo, 19 CSR 30-1.031(1)-(2), 19 CSR 30-1.034(1)(A)-(B), 21 C.F.R. §1301.75(b), 21 C.F.R. § 1301.71(a) and 20 CSR 2220-2.010(1)(H).

JOINT CONCLUSIONS OF LAW

40. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit pursuant to 20 CSR 2220-2.010(1)(O) which states:

> (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo. 20 CSR 2220-2.010(1)(O).

41. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under Section 338.285, RSMo, which states:

> The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

42. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under Section 338.055, RSMo, which states in relevant parts:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> * * *
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> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
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> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government. §338.055.2(6), and (15), RSMo.
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> * * *

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

1. Respondent's pharmacy permit numbers 2004023122 and 2009008060 shall be placed on **PROBATION** for a period of two (2) years. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

A. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

D. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not e deemed or taken as any part of the time of discipline so imposed.

E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of the disciplinary order.

F. Respondent shall not serve as an intern training facility for interns.

G. Respondent shall select an independent pharmacist consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. The consultant shall be a Missouri licensed

pharmacist whose license is current and not subject to disciplinary action by the Board. Respondent shall submit documentation and credentials of its chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall subject a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the Board office attesting to the pharmacy's compliance or noting deficiencies for each visit made. The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense.

H. Consultant shall perform an audit and reconciliation on all controlled substances and all tramadol-containing products on a semi-annual basis coinciding with the consultant visits above. The consultant shall report the results of each reconciliation to the Board office.

I. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

J. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

K. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

2. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____REQUESTS

_____DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

MISSOURI CVS PHARMACY, LLC
d/b/a CVS/PHARMACY #5645

By: _____
Richard B. Mazzoni, R.Ph.
As Authorized Agent for
MISSOURI CVS PHARMACY, LLC
d/b/a CVS/PHARMACY #5645

Date: 2/29/2012

COOK, VETTER, DOERHOFF AND LANDWEHR

by _____
JOHN LANDWEHR

ATTORNEY FOR RESPONDENT

3-15-12

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____
KIMBERLY GRINSTON
Executive Director

Date: 5-7-12

NEWMAN, COMLEY & RUTH P.C.

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